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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT PAPER NUMBER

1645

DATE MAILED: 02/04/2004

17

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/881,556

Applicant(s)

SIMONSEN, J. NEIL

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,4,6-8 and 32-35 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1,3,4,6-8 and 32-35 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

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DETAILED ACTION

REQUEST FOR CONTINUED EXAMINATION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114.

Additionally Applicants amendment filed September 25, 2003 (Paper Number 14) has been entered. Claims 2, 5 and 9-31 have been canceled and new claims 32-35 have been added, consequently claims 1, 3-4, 6-8 and 32-35 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 1, 3-4, and 6-8 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained. This is a written description rejection.

Applicants are asserting that the claims comply with the written description requirement of 35 USC 112 first paragraph. In particular, Applicants point to Example 14 of the guidelines, which claims a variant of a specified sequence that are "at least 95% identical" to the reference

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sequence and that catalyze the reaction of A to B. Applicants further assert that the nucleic acid sequence of SEQ ID NO: 3 has been cloned and the protein of SEQ ID NO: 4 has been obtained. Applicants further assert that detailed procedures for finding immunogenic portions of the proteins (i.e., Specification pages 9-10) as well as tests for determining immunogenicity are well known in the art.

Applicants arguments have been fully considered but are not found to be fully persuasive.

Applicants assert that Example 14 of the guidelines, which claims a variant of a specified sequence that are "at least 95% identical" to the reference sequence and that catalyze the reaction of A to B meets the written description guidelines. This point is readily agreed upon. However, the instant application does not meet the same standards set forth in Example 14. Example 14 clearly identifies the members of the genus by those which have a particular activity (i.e., catalyze the reaction of A to B). One of skill in the art would be able to readily identify which members of the genus possessed the claimed activity given that assays for detecting this activity are well known in the art. However, Applicants claims do not recite any activity of the protein. Rather, the claim recites "an equivalent or enhanced immunological response." What assay is used to determine this property? Furthermore, what is the response being measured (e.g., titer level of IgG, IgM, IgA, IgD, IgE, T cell response, etc.)? Without a clear indication of how "equivalent or enhanced immunological response" is being measured, one of skill in the art would simply be unable to determine the members of the claimed genus.

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Claims 1, 3-4 and 6-8 recite an isolated nucleic acid molecule comprising a coding sequence for an immunogenic *C. parvum* polypeptide, wherein the polypeptide is selected from the group consisting of (a) a polypeptide comprising the sequence of amino acids depicted at amino acid positions 1-193 of Figure 2B (SEQ ID NO: 4) or an immunogenic fragment thereof comprising at least 15 nucleotides and that elicits an equivalent or enhanced immunological response as compared to the polypeptide comprising the sequence of amino acids depicted at amino acid positions 1-193 of Figure 2B, and (b) a polypeptide with at least 90% sequence identity to a polypeptide comprising the sequence of amino acids depicted at amino acid positions 1-193 of Figure 2B (SEQ ID NO: 4) and that elicits an equivalent or enhanced immunological response as compared thereto.

The specification and claims do not indicate what distinguishing attributes are shared by the members of the genus. Thus, the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, SEQ ID NO: 3 encoding SEQ ID NO: 4 alone is insufficient to describe the genus. Thus, Applicant's have not described a function which is shared by SEQ ID NO: 3 encoding SEQ ID NO: 4 which would adequately describe the genus. One of skill in the art would reasonably conclude that the

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disclosure fails to provide a representative number of species to describe the genus. Thus, applicant was not in possession of the claimed genus.

Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Lts.*, 18 USPQ2d 1016.

Applicants are directed to the Revised Interim Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, 1 "Written Description" Requirement, Federal Register, Vol. 64, No. 244, pages 71427-71440, Tuesday December 21, 1999.

For reasons of record in Paper Number 15, as well as the reasons set forth above, this rejection is maintained.

2. The rejection of claim 3 under 35 U.S.C. 112, second paragraph, as being vague and indefinite in the recitation of "at least about 15 nucleotides." is withdrawn in view of Applicants amendment.

Claim Rejections - 35 USC § 102

3. The rejection of claims 1, 4, and 7-8 under 35 U.S.C. 102(e) as being anticipated by Perryman *et al* is withdrawn in view of Applicants amendment.

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The following new grounds of rejection are applied to the newly filed and amended claims:

Claim Rejections - 35 USC § 112

4. Claims 1, 3-4, 6-8 and 32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are vague and indefinite in the recitation of “equivalent or enhanced immunological response.” For instance, what immunological response is being measured to determine if the response is equivalent or enhanced? (e.g., titer of IgG, IgM, IgA, IgD, IgE, a T cell response, chemotactic properties, etc.). Without a clear definition as to the metes and bounds of what property of immunological response is being measured, one of skill in the art would be unable to determine the metes and bounds of the claimed invention.

5. Claims 1, 3-4, 6-8 and 32-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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The claims are vague and indefinite in the recitation of "amino acid positions 1-193 of Figure 2B." Applicants are respectfully directed to Figure 2B and will note that there are no amino acids recited at all in Figure 2B, only nucleotides. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1, 4, and 6-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Wittrup et al.

The claims are directed to an isolated nucleic acid molecule comprising a coding sequence for an immunogenic *C. parvum* polypeptide, wherein the polypeptide is selected from the group consisting of (a) a polypeptide comprising the sequence of amino acids depicted at amino acid positions 1-193 of Figure 2B (SEQ ID NO: 4) or an immunogenic fragment thereof comprising at least 15 nucleotides and that elicits an equivalent or enhanced immunological response as compared to the polypeptide comprising the sequence of amino acids depicted at amino acid positions 1-193 of Figure 2B, and (b) a polypeptide with at least 90% sequence identity to a polypeptide comprising the sequence of amino acids depicted at amino acid positions 1-193 of

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Figure 2B (SEQ ID NO: 4) and that elicits an equivalent or enhanced immunological response as compared thereto.

Wittrup et al (US Patent Number 5,773,245) disclose of methods for increasing secretion of an overexpressed gene product in a host cell. Wittrup et al further disclose of DNA encoding SEQ ID NO: 18 to increase the secretion of an overexpressed gene product in a host cell. (See columns 4-6 and claims).

It is noted that amino acids 461-467 (Pro-Ile-Lys-Glu-Asn-Gly-His) of the sequence disclosed by Wittrup et al are identical to amino acids 177-183 of SEQ ID NO: 4 of the instant invention. Accordingly, the nucleic acid disclosed by Wittrup et al is deemed to comprise an "immunogenic fragment" of the claimed nucleic acid molecule. The nucleic acid disclosed by Wittrup is deemed to elicit an "equivalent or enhanced immunological response" compared to the protein (SEQ ID NO: 4) of the instant invention, given that the nucleic acid meets 100% of the structural requirements recited in the claim (i.e., immunogenic fragment comprising at least 15 nucleotides).

Claims 32-35 are free of the prior art of record, and would be allowable if amended into independent form (e.g., An isolated nucleic acid encoding an immunogenic polypeptide comprising SEQ ID NO: 4).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

February 2, 2004